

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it purported and was represented to possess, namely, 110 micrograms of vitamin B₁₂ per cubic centimeter; and 502 (a)—the label statement "Each cc. contains: Liver Extract U. S. P. 10 mcgm. Cyanocobalamine. Vit. B₁₂ 100 Mcg." was false and misleading.

DISPOSITION: 1-25-55. Default—destruction.

4754. Chocolated Cokozine. (F. D. C. No. 37631. S. No. 6-629 M.)

QUANTITY: 94 8-oz. btls. and 71 1-pint btls. at Cincinnati, Ohio.

SHIPPED: Between 1943 and 1950, from New York, N. Y.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amount of vitamin B₁.

LIBELED: 1-31-55, S. Dist. Ohio.

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it was represented to possess, namely, 10 milligrams of vitamin B₁ (thiamine hydrochloride) per fluid ounce; and 502 (a)—the label statement "Contains in One Fluid Ounce: * * * Thiamin hydrochloride. . . . 10 mg." was false and misleading.

The libel alleged also that two other articles, namely, thiamine chloride elixir and malt syrup with halibut liver oil, were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3-3-55. Default—destruction.

4755. Rauwolfia serpentina. (F. D. C. No. 37594. S. Nos. 11-927/8 M.)

QUANTITY: 1 barrel containing 86 lbs. and 2 100-lb. drums at Brooklyn, N. Y.

SHIPPED: (2-drum lot) 4-19-54, from Tuticorin, India, by J. M. L. Danusu & Co.; (1-barrel lot) 5-4-54, from Chicago, Ill., by Armour Laboratories.

LIBELED: 1-12-55, E. Dist. N. Y.

CHARGE: 501 (d) (2)—the article in each lot was represented as *Rauwolfia serpentina*, and a substance other than *Rauwolfia serpentina* had been substituted in whole or in part therefor when shipped; 502 (a)—the label designations (1-barrel lot) "Rauwolfia Serpentina" and (2-drum lot) "Pow. Rauwolfia Serpentina" were false and misleading since such designations represented and suggested that the article in each lot consisted wholly of *Rauwolfia serpentina*, which was not the case; and 502 (i) (3)—the article in each lot was offered for sale under the name of another drug.

DISPOSITION: 3-9-55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4756. Testo-Glan Male Formula and Fem-Tone Female Formula. (Inj. No. 275.)

COMPLAINT FOR INJUNCTION FILED: 3-9-54, E. Dist. N. Y., against Leo Shine, t/a Glanex Products, Floral Park, N. Y.

LABEL IN PART: "Testo-Glan Male Formula Regular Strength Each capsule contains—Hormonal activity as found in wheat—Testosterone (Male Sex Hormone) 0.067 mcg. Vitamin E 0.034 mgms. Survival Factor + Vitamin B 1 5 mg. 500% MDR Vitamin B 2 3.5 mg. 175% MDR Niacinamide 15 mg. [or "Double Strength Each capsule contains—

*See also Nos. 4741, 4742, 4746, 4750, 4752-4755.

Hormonal activity as found in wheat—Testosterone (Male Sex Hormone) 0.067 mcg. Vitamin E 0.034 mgms. Survival Factor + Vitamin B 1 10 mg. 1000% MDR Vitamin B 2 7 mg. 350% MDR Niacinamide 30 mg.”] Contents 60 Capsules Sole Distributors Glanex Products * * * Floral Park, N. Y. Directions As a dietary supplement, take 2 capsules daily” and “Fem-Tone Female Formula Contents 60 Capsules Each capsule contains—Hormonal activity as found in wheat—Estrone (Female Sex Hormone) 0.005 mcg. Vitamin E 0.034 mgms. Survival Factor + Vitamin B 1 5 mg. 500% MDR Vitamin B 2 3.5 mg. 175% MDR Niacinamide 15 mg. Sole Distributors Glanex Products 6 North Tyson Avenue Floral Park, N. Y. Directions As a dietary supplement, take 2 capsules daily.”

ACCOMPANYING LABELING: Folder entitled “For Men Past 40 Testo-Glan The New Extra Safe Male Power Formula” and a form letter addressed to “Dear Friend” and beginning with the words “Men past 40 everywhere are praising Testo-Glan.”

CHARGE: The complaint alleged that the defendant had been and still was introducing into interstate commerce the above-mentioned articles which were misbranded within the meaning of 502 (a) by reason of the following false and misleading representations in their labeling:

(1) That the *Testo-Glan Male Formula* (regular strength and double strength) contained physiologically active glandular substances; that the glandular constituents of the article were of value in overcoming glandular deficiencies in the human male; that the article would increase male power; that it was an adequate and effective treatment for male sexual weakness, mental depression, loss of appetite, digestive disturbance, loss of muscle power, listlessness, headaches, loss of vigor, nervousness, vague aches and pains, sleeplessness, and irritability; and that it contained hormonal activity equivalent to therapeutically significant amounts of testosterone;

(2) That the *Fem-Tone Female Formula* would restore sexual desire in women; that it was an adequate and effective treatment for fatigue, loss of appetite, nervousness, dizziness, headaches, vague aches and pains, weakness, mental depression, and sleeplessness; and that it contained hormonal activity equivalent to therapeutically significant amounts of estrone.

The complaint alleged further that there were no known methods of demonstrating the presence or absence of the minute quantities of testosterone activity claimed to be present in the *Testo-Glan Male Formula* and the minute quantities of estrone activity claimed to be present in the *Fem-Tone Female Formula*; that the commonly employed therapeutic dose of testosterone given orally was at least 1,000 times the quantity that would be supplied in the recommended dosage of the *Testo-Glan Male Formula* based on the label statement of testosterone activity content; that the quantity of estrone activity claimed to be present in the *Fem-Tone Female Formula* was likewise totally insignificant; that the statements in the labeling of the articles conveyed to the usual and ordinary purchaser the impression that the *Testo-Glan Male Formula* contained hormonal activity equivalent to therapeutically significant amounts of testosterone and that the *Fem-Tone Female Formula* contained hormonal activity equivalent to therapeutically significant amounts of estrone, whereas such was not the case; and, that even if the articles did contain significant amounts of hormones, the articles would not accomplish the rejuvenating effects claimed for them.

DISPOSITION: 4-19-54. The defendant having consented, the court entered a decree permanently enjoining the defendant against the introduction into inter-

state commerce of "Testo-Glan Male Formula" (regular strength and double strength) and "Fem-Tone Female Formula," or any similar article of drug which would bear a label or would be accompanied by labeling containing false and misleading representations of the nature alleged in the complaint.

4757. Testo-Glan Male Formula. (Inj. No. 275.)

PETITION FILED: On 9-15-54, in the E. Dist. N. Y., the U. S. attorney filed a petition for an order to show cause why Leo Shine, t/a Glanex Products and Medical Products, Floral Park, N. Y., should not be punished for criminal contempt of the permanent injunction which had been entered against him on 4-19-54 (preceding notice of judgment No. 4756).

CHARGE: The petition alleged that, following the entry of the injunction, and between 4-28-54 and 5-27-54, the defendant caused interstate shipments of *Testo-Glan Male Formula* (regular strength and double strength) to be made from Floral Park, N. Y., to Dayton and Niles, Ohio; Norfolk, Va.; Los Angeles, Calif.; Chicago, Ill.; Atlanta, Ga.; and Hartford, Conn.; that, when so shipped, the article was misbranded under 502 (a) in that its labeling contained false and misleading representations that the article contained physiologically active glandular substances; that the glandular constituents of the article were of value in overcoming glandular deficiencies in the human male; that the article would increase male power; that it was an adequate and effective treatment for male sexual weakness, mental depression, loss of appetite, digestive disturbance, loss of muscle power, listlessness, headaches, loss of vigor, nervousness, vague aches and pains, sleeplessness, and irritability; that it contained hormonal activity equivalent to therapeutically significant amounts of testosterone; and, that by reason of such shipments, the defendant was in criminal contempt of the permanent injunction.

DISPOSITION: On 9-16-54, the order to show cause was issued, and on 10-11-54, the defendant pleaded guilty to violation of the injunction. On 11-14-54, the court fined the defendant \$500.

4758. Alfa-Tone and Cab-Ext (2 seizure actions). (F. D. C. No. 37357. S. Nos. 64-766/7 L.)

QUANTITY: 1,524 unlabeled 90-tablet btls. and 250 labeled 90-tablet btls. of *Alfa-Tone* and 650 unlabeled 50-tablet btls. and 500 labeled 50-tablet btls. of *Cab-Ext* at Milton-Freewater, Oreg., in the possession of Dr. A. V. Downs, D. C.

SHIPPED: 7-7-54 and 7-14-54, from Lamar, Colo.

LABEL IN PART: (Btl.) "*Alfa-Tone* Each tablet contains 4 grs. water soluble Alfalfa Extract. 2 grs. of Alfalfa Seed Extract. 0.1 gr. of Chlorophyll" and "*Cab-Ext* Each tablet contains 400 Mg. of cabbage extract. As an aid in relieving ulcers and inflammation of stomach."

ACCOMPANYING LABELING: Loose labels designated "*Alfa-Tone*" and "*Cab-Ext*" and leaflets designated "*Alfa-Tone* As An Aid For Hay Fever, Low Vitality, Arthritis, Neuritis, Anemia, and Low Blood Pressure" and "*Cabbage Juice*."

RESULTS OF INVESTIGATION: Both articles were shipped from Lamar, Colo., in unlabeled bottles, and, upon their receipt by the consignee, the above-described labels were applied to a number of bottles. The leaflets were printed locally for the consignee and were distributed with the articles to various health store accounts serving the retail trade.

LIBELED: On or about 1-25-55, Dist. Oreg.

CHARGE: 502 (a)—the labeling of the articles while held for sale contained false and misleading representations that the *Alfa-Tone* was an adequate and